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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,912	09/28/2005	Shinya Komura	Q90112	4288
23373 7590 01/07/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
CHOL PETER Y				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,912

Applicant(s)

KOMURA ET AL.

Examiner

PETER Y. CHOI

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Nanostructured Fibers via Electrospinning" to Bognitzki in view of USPN 4,701,267 to Watanabe.

Regarding claims 1-12, Bognitzki teaches a fabric characterized by an aggregate of filaments composed of a thermoplastic polymer and by having a mean fiber size of 0.1-20 μ m, wherein any given lateral cross-section of each of the filaments is an irregular shape (see entire document including first-twelfth paragraphs, Figure 3).

Regarding claims 1-12, Bognitzki teaches that the fabric may be used in filter applications and biomedical applications (Bognitzki, first paragraph). However, Bognitzki does not appear to teach that the fabric is nonwoven and that the mean apparent density is in the range of 10-95 kg/m³. Since Bognitzki is silent with regards to the specific structure and density of the fabric, it would have been necessary and thus obvious to look to the prior art for conventional filters and biomedical applications. Watanabe provides this conventional teaching showing that it is known in the medical industry fabric art to form a nonwoven fabric comprising thermoplastic microfibers wherein the density of the fabric is from 0.01 g/cm³ to 0.7 g/cm³ (Watanabe, column 2 lines 5-22, column 3 lines 5-18). Therefore, it would have been obvious to

one having ordinary skill in the art at the time the invention was made to make the microfiber fabric of Bognitzki, wherein the fabric is a nonwoven fabric having a fabric density of from 0.01 g/cm^3 to 0.7 g/cm^3 , as taught by Watanabe, motivated by the expectation of forming a conventional medical industry fabric according to specifications known in the art which are suitable for the desired application as a wound dressing or filter.

Regarding claim 2, the irregular shape is at least one type selected from the group consisting of $0.1\text{-}1\mu\text{m}$ pits on the filament surfaces, $0.1\text{-}1\mu\text{m}$ protrusions on the filament surfaces, pits formed in a linear fashion in the fiber axis direction on the filament surfaces, protrusions formed in a linear fashion in the fiber axis direction on the filament surfaces and micropores in the filament surfaces (Bognitzki, tenth-twelfth paragraphs, Figure 3).

Regarding claim 3, the mean fiber size is $0.1\text{-}5\mu\text{m}$ (Bognitzki, seventh paragraph).

Regarding claim 4, Bognitzki in view of Watanabe teaches that the nonwoven fabric thickness is $100\mu\text{m}$ or greater (Watanabe, column 4 lines 37-46).

Regarding claims 5-12, the thermoplastic polymer is a polymer which is soluble in a volatile solvent (Bognitzki, fifth paragraph).

Regarding claims 6 and 7, the thermoplastic polymer which is soluble in a volatile solvent is an aliphatic polyester and the aliphatic polyester is polylactic acid (Bognitzki, fifth-tenth paragraphs, Figure 3).

Regarding claims 8-12, Bognitzki in view of Watanabe does not appear to teach that the volatile solvent is a mixed solvent comprising a volatile good solvent and a volatile poor solvent, that the ratio of the volatile poor solvent and volatile good solvent in said mixed solvent is in the range of (23:77) to (40:60), based on weight, that the volatile good solvent is a halogen-

containing hydrocarbon, that the volatile poor solvent is a lower alcohol, and that the lower alcohol is ethanol. It should be noted that Applicants' specification teaches that polylactic acid is soluble in volatile solvents, such as those comprising a halogen-containing hydrocarbon and ethanol in the claimed ratio, and therefore such solubility appears to be inherent to the polylactic acid polymer (*see* Applicants' specification, page 7 line 23 to page 8 line 34). Additionally, it should be noted that a volatile good solvent and a volatile poor solvent, and therefore the presence of a halogen element-containing hydrocarbon and ethanol, are not actually required by the claim; the only requirement is that the polymer is soluble in the volatile solvent. Additionally, the prior art combination appears to meet the claim limitations as the thermoplastic polymer in the prior art is substantially similar or identical to the claimed thermoplastic polymer formed by a substantially similar electrospinning process as the claimed invention, absent evidence to the contrary.

3. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pub. No. 2002/0192449 to Hobbs in view of Watanabe.

Regarding claims 1-12, Hobbs teaches a nonwoven fabric characterized by being an aggregate of filaments composed of a thermoplastic polymer, and by having a mean fiber size of 0.1-20 gm, wherein any given lateral cross-section of each of the filaments is an irregular shape (*see* entire document including paragraphs 0001, 0010-0017, 0030, 0047, 0070, 0107-0110, 0114, 0116, 0118, 0121).

Regarding claims 1-12, Hobbs does not appear to teach that the fabric has a mean apparent density in the range of 10-95 kg/m³. Since Hobbs is silent with regards to specific

density of the fabric, it would have been necessary and thus obvious to look to the prior art for conventional specifications. Watanabe provides this conventional teaching showing that it is known in the medical industry fabric art to form a nonwoven fabric comprising thermoplastic microfibers wherein the density of the fabric is from 0.01 g/cm^3 to 0.7 g/cm^3 (Watanabe, column 2 lines 5-22, column 3 lines 5-18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the nonwoven microfiber fabric of Hobbs having a fabric density of from 0.01 g/cm^3 to 0.7 g/cm^3 , as taught by Watanabe, motivated by the expectation of forming a conventional medical industry fabric according to specifications known in the art which are suitable for the desired application as a wound dressing or filter.

Regarding claim 2, the irregular shape is at least one type selected from the group consisting of $0.1\text{-}1\text{ }\mu\text{m}$ pits on the filament surfaces, $0.1\text{-}1\text{ }\mu\text{m}$ protrusions on the filament surfaces, pits formed in a linear fashion in the fiber axis direction on the filament surfaces, protrusions formed in a linear fashion in the fiber axis direction on the filament surfaces and micropores in the filament surfaces (Hobbs, paragraphs 0010, 0011, 0021).

Regarding claim 3, the mean fiber size is $0.1\text{-}5 \text{ }\mu\text{m}$ (Hobbs, paragraphs 0010, 0015).

Regarding claim 4, the nonwoven fabric thickness is $100 \text{ }\mu\text{m}$ or greater (Hobbs, paragraphs 0047, 0070, Claim 41).

Regarding claims 5-12, the thermoplastic polymer is a polymer which is soluble in a volatile solvent (Hobbs, paragraph 0030).

Regarding claim 6, the thermoplastic polymer which is soluble in a volatile solvent is an aliphatic polyester (Hobbs, paragraph 0030).

Regarding claim 7, the aliphatic polyester is polylactic acid (Hobbs, paragraph 0030).

Regarding claims 8-12, Hobbs in view of Watanabe does not appear to teach that the volatile solvent is a mixed solvent comprising a volatile good solvent and a volatile poor solvent, that the ratio of the volatile poor solvent and volatile good solvent in said mixed solvent is in the range of (23:77) to (40:60), based on weight, that the volatile good solvent is a halogen-containing hydrocarbon, that the volatile poor solvent is a lower alcohol, and that the lower alcohol is ethanol. It should be noted that Applicants' specification teaches that polylactic acid is soluble in volatile solvents, such as those comprising a halogen-containing hydrocarbon and ethanol in the claimed ratio, and therefore such solubility appears to be inherent to the polylactic acid polymer (*see* Applicants' specification, page 7 line 23 to page 8 line 34). Additionally, it should be noted that a volatile good solvent and a volatile poor solvent, and therefore the presence of a halogen element-containing hydrocarbon and ethanol, are not actually required by the claim; the only requirement is that the polymer is soluble in the volatile solvent. Additionally, the prior art combination appears to meet the claim limitations as the thermoplastic polymer in the prior art is substantially similar or identical to the claimed thermoplastic polymer formed by a substantially similar electrospinning process as the claimed invention, absent evidence to the contrary.

Response to Arguments

4. Applicants' arguments filed November 5, 2007, have been fully considered but they are not persuasive. Applicants argue that the claimed invention can be used as cell growth matrices in the field of regenerative medicine and therefore additional requirements must be met. Additionally, Applicants argue that although Watanabe broadly discloses a nonwoven fabric

having a bulk density of 0.01-0.7 g/cm³, Watanabe does not provide an enabling disclosure of the claimed nonwoven fabric having a bulk density of 10-95 kg/m³. Additionally, Applicants argue that the specific production method comprises a step wherein a thermoplastic polymer is dissolved in a mixed solvent composed of a volatile good solvent and a volatile poor solvent, a step wherein the resulting solution is spun by an electrospinning method, and a step wherein the nonwoven fabric is formed, and that neither Hobbs nor Watanabe disclose or suggest such a method.

Regarding Applicants' arguments, Examiner respectfully disagrees. First, it should be noted that electrospinning or an electrospinning method or an electrospun fiber or an electrostatically formed fiber is not claimed anywhere in the claims. Second, it should be noted that Applicants only claim a nonwoven fabric. The fabric is not claimed to be used or intended to be used as cell growth matrices in the field of regenerative medicine. Third, regarding the specific production method, Applicants only claim the product comprising a nonwoven fabric. Product by process limitations are absent from the claimed invention. As set forth above, a volatile good solvent and a volatile poor solvent, and therefore the presence of a halogen element-containing hydrocarbon and ethanol, are not actually required by the claim; the only requirement is that the polymer is *soluble* in the volatile solvent. Additionally, as set forth above, Applicants' specification teaches that polylactic acid is soluble in volatile solvents, such as those comprising a halogen-containing hydrocarbon and ethanol in the claimed ratio, and therefore such solubility appears to be inherent to the polylactic acid polymer (*see* Applicants' specification, page 7 line 23 to page 8 line 34). Additionally, the prior art combination appears to meet the claim limitations as the thermoplastic polymer in the prior art is substantially similar

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or identical to the claimed thermoplastic polymer formed by a substantially similar electrospinning process as the claimed invention, absent evidence to the contrary. Applicants only argue that the process limitations solve a problem, but the arguments are not commensurate in scope with the claimed invention since the claimed invention does not require any method steps to form the claimed invention.

Regarding Applicants' argument that Watanabe does not provide an enabling disclosure of a nonwoven fabric having a bulk density which anticipates or is obvious over the claimed invention, Examiner respectfully disagrees. A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation. Every patent is presumed valid (35 U.S.C. 282), and that presumption includes the presumption of operability. Further, since in a patent it is presumed that a process if used by one skilled in the art will produce the product or result described therein, such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. It is to be presumed also that skilled workers would as a matter of course, if they do not immediately obtain desired results, make certain experiments and adaptations, within the skill of the competent worker.

Watanabe clearly teaches the use of polyester microfibers having an average diameters of from 0.3 μ m to less than 3 μ m (Watanabe, column 3 lines 5-18), which is similar to the polyester microfibers of Hobbs (Hobbs, paragraphs 0010-0017, 0030). Watanabe teaches that it was known in the art to form a nonwoven fabric comprising thermoplastic microfibers wherein the

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density of the fabric is from 0.01 g/cm^3 to 0.7 g/cm^3 . Clearly, the density range overlaps and encompasses the claimed density. A prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness. Additionally, Applicants have not provided evidence of the criticality of the claimed range and that the claimed range achieves unexpected results relative to the prior range.

Conclusion

5. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER Y. CHOI whose telephone number is (571)272-6730. The examiner can normally be reached on Monday - Friday, 08:00 - 15:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew T Piziali/
Primary Examiner, Art Unit 1794

/Peter Y. Choi/
Examiner, Art Unit 1794
January 3, 2008